

Group C. Monitoring AIDS Patient Therapy – CD4, Viral Load, and Drug Resistance

General Recommendations:

- Each country should have the capability to provide relevant monitoring for both pediatric and adult patients.
- Each reference laboratory should have arrangements for backup capabilities.
- Although not ideal, other options include transporting specimens or referring patients. These options may be most useful in early years while laboratory infrastructure is being built.
- Each country should have a training program that will sustain the laboratory capability, not only for the first year, but also for subsequent years.
- Each reference laboratory should have both internal and external QA and QC.
- Each testing laboratory should develop SOPs (training, QA/QC, reagent acquisition, equipment maintenance).
- All prices on equipment and reagents should be negotiated.
- The experience in Brazil suggests that packages that include equipment, reagents, service, consumables, and training can be negotiated at a per test cost.

Levels of Laboratory System: Necessary equipment to perform CD4 testing

- Central Laboratory (laboratory with a patient volume >15,000/year)
 - Physical requirements
 - Reliable electricity
 - Laboratory management
 - Data management
 - Established QA program in place
 - Adequate sample processing capability
 - Air conditioning
 - Infrastructure
 - Reliable re-supply system
 - Human capital (supervisory and bench)
 - Biosafety, including adequate waste disposal
 - -70°C Freezer
 - Capability of performing CBC
 - Blood mixer and vortex mixer
 - Instrument service contract
 - Two refrigerators
 - Microscope
 - Class 2 Biological safety cabinet
 - Centrifuges
 - Laboratory quality water
 - Test equipment
 - High end flow cytometer (estimated cost--\$150,000): possible choices:
 - BD FACSCalibur

- Beckman-Coulter XL with batch loader
- Backup, FACSCount
- Intermediate Laboratory (laboratory with a patient volume 2,001 – 15,000/year)
 - Physical Requirements: same as for Level One laboratory
 - Testing Equipment: dedicated flow cytometer (estimated \$30-40K): possible choice – FACSCount (may need double shifts or second instrument)
- Peripheral Laboratory (laboratory with a patient volume up to 2,000/year)
 - Physical Requirements
 - Working microscope, including light source
 - Refrigerator
 - Reliable electricity
 - Laboratory grade water
 - Testing Equipment: manual CD4 tests (10 tests/technician/day, \$4-\$8 per test); choices include Dynabeads (Dynal) and Cytospheres (Coulter).

First Year and Beyond Plan for Viral Load Testing and HIV Drug Resistance Monitoring

- During the first year, the capacity for viral load testing and resistance monitoring should be developed in the central laboratory, primarily for program evaluation.
- Countries are encouraged to participate in the WHO HIV Drug Resistance Surveillance Network.
- To ensure long-term successful patient care, a funding mechanism should be established to support continuous program evaluation and program improvement, using virologic endpoints (viral load and HIV drug resistance testing). This goal can be accomplished through in-country partners and or regional/international partners and may be performed through periodic evaluation of the cost/benefit ratio of such technology.